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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,987	10/01/2001	Andrew D. Murdin	032931-0253	7970

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	12

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,987	MURDIN ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/4/03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1,3-7,15,17,20-35 and 37-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 8-14, 16, 18-19 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed on 12/04/2002, paper # 10 is acknowledged. Claims 1, 2, 8, 9, 18, 19, 21, 27 and 28 have been amended. Claims 1-39 are pending in the application.

Priority

2. This application is a national stage entry of PCT/CA99/01230_ 12/23/1999

Which Claims Priority from Provisional Application 60113280

Which Claims Priority from Provisional Application 60113281

Which Claims Priority from Provisional Application 60113282

Which Claims Priority from Provisional Application 60113283

Which Claims Priority from Provisional Application 60113284

Which Claims Priority from Provisional Application 60113285

Which Claims Priority from Provisional Application 60114050

Which Claims Priority from Provisional Application 60114056

Which Claims Priority from Provisional Application 60114057

Which Claims Priority from Provisional Application 60114058

Which Claims Priority from Provisional Application 60114059

Which Claims Priority from Provisional Application 60114061

According to the priority statement of 9/27/01, it appears that priority is being claimed to a large number of provisional applications as above. These applications appear to be drawn to unrelated subject matter and are either not available for consideration or for which consideration to determine support for the instantly claimed subject matter would require an undue burden. Accordingly, the subject matter defined in the elected claims, drawn to SEQ ID NO: 1 have an effective filing date of 12/23/1999 that of the PCT/CA99/01230 application because SEQ ID NO: 1 is disclosed in PCT/CA99/01230 application.

Applicants are requested to provide the serial number and specific page numbers of any provisional application to which priority is desired which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession and fully enabled of prior to 12/23/1999.

Information Disclosure Statement

3. Information Disclosure Statement filed on 10/1/01 (Paper # 5) is acknowledged and a signed copy is attached to this Office action.

Drawings

4. The drawings are objected to by the draftsperson under 37 C.F.R. 1.84 or 1.152. See attached PTO-948 for details.

Specification - Informalities

5. Claims should begin with "I claim" or "'We claim" or "What is claimed is".

There is no abstract of the claimed invention present in the application.

Election/Restriction

6. Applicant's election of Group II, Claims 1-19, 25 and 36 with respect to SEQ.ID.NO: 1 with traverse in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the search and examination of the entire application would not be an undue burden. This is not found persuasive.

Applicant states that groups I-V are linked by the common generic special technical feature as defined by PCT Rule 13.2 (37CFR1.475(a)) and therefore all the claims with respect

to SEQ.ID.NO: 1 and 14 should be examined. It is the position of the Office that the expression special technical features shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. However, Kalman et al, (GENEMBL, Accession number AE001641, 12/1/98; reference A 57 on PTOL-1449). Disclose i.e., a nucleic acid molecule comprising SEQ.ID.NO: 1, therefore it does not constitute a special technical feature by definition. Therefore, lack of unity is present.

Concerning the burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The DNA database searches required by each of the sequences and the literature searches for each of the sequences, both of which are particularly relevant in this art, are not co-extensive and are much more important in evaluating the burden of search. For example, search and examination issues for nucleic acid vaccines are different and would not encompass protein vaccines. Further, it is doubted that applicants would readily accept the rejection of one sequence by the application of art teaching another sequence. Clearly different searches and issues are involved in the examination of each group.

The requirement is still deemed proper and is therefore made FINAL.

7. Claims 2, 8-14, 16, 18-19 and 36 are under examination with respect to SEQ.ID.NO: 1. Claims 1, 3-7, 15, 17 and 25 are withdrawn from elected Group II invention as the claims are not drawn to an elected invention, SEQ.ID.NO: 1. Applicants indicate that with respect to the election, they elect SEQ ID NO: 1 and 14. It is specifically noted, that a species election was not imposed. Each of the recited sequences is deemed patentably distinct from each other and applicants were required to elect a single product for examination on the merits. As such, examination of the single product will be restricted to the nucleic acid of SEQ ID NO: 1.

8. Claims 20-24, 26-35 and 37-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Double Patenting

9. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 2, 8-14, 16, 18-19 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-71, especially claims 33-51, 57 and 68 of copending Application No. 09/886,468. Although the conflicting claims are not identical, they are not patentably distinct from each other because in both applications applicant is claiming a nucleic acid molecule SEQ.ID.NO: 1, vaccine and pharmaceutical composition comprising SEQ.ID.NO: 1 and nucleic acid probes comprising SEQ.ID.NO: 1 and a method of preventing Chlamydia infection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC 101

11. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

12. Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is drawn to a nucleic acid, product of nature. Products of nature are not patentable because they do not reflect the "hand of man" in the production of the product or manufacturing process. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. 5upp 68 (1967). See also American Wood v. Fiber Disinterarating Co., 90 US 566 (1974);American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Innoculant Co. 33 US 127 (1948). It is suggested to include the terminology " an isolated nucleic acid or isolated polynucleotide " to overcome the rejection.

Claim Rejections - 35 U.S. C. 112, first paragraph

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 2, 8-14, 16, 18-19 and 36 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the

interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114, pp 32639-32645 (also available at www.uspto.gov). This is a written description rejection.

The specification also broadly describes a gene specifically by a polynucleotide sequence of SEQ ID NO: 1. The specification broadly describes as part of the invention isolated polynucleotides encoding the polypeptide of SEQ ID NO: 14 (CPN 100686 RY 54), which is a "putative 98kDouter membrane protein (see pages 8-10). The actual biological function of the polypeptide encoded thereby and represented as SEQ ID NO: 14 and a method of preventing infection is not set forth in this specification. Applicants also broadly describe the invention as embracing any substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides found in the encoding or reference sequence by use of language in which a specified percent of amino acids can be changed in the polypeptide .As depending from these are the vectors, host cells, vaccines, diagnostics and methods of producing the polypeptide. The-claims encompass polynucleotide sequences comprising SEQ ID NO: 1, sequences that have a recited degree of change as compared to a reference nucleic acid sequence encoding SEQ ID N0: 14, as compared to a sequence which encodes a polypeptide encoded by SEQ ID NO: 1, complements or anti-sense sequences, immunogenic homologs that correspond to sequences from other species, mutated sequences, allelic variants and comprising nucleic acids of SEQ ID NO--1 or nucleic acids encoding SEQ ID NO: 14. None of these sequences meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification only discloses a polynucleotide sequence consisting of SEQ ID NO: 1 which corresponds to the polynucleic acid sequence encoding the Chlamydia pneumoniae species of the protein which comprises SEQ ID N0: 14. An isolated polynucleotide comprising a nucleotide sequence encoding SEQ ID NO: 14, is also described by way of the written description in view of the art established principle of wobble variants of triplet codons for particular bacterial amino acids as described in basic Microbiology textbooks. Thus, an isolated polynucleotide sequence comprising of SEQ ID NO: 1 meets the written description provision of 35 U.S.C. 112, first paragraph for the reasons set forth below.

The specification fails to teach a single variant or homolog of a polypeptide sequence of encoded by SEQ ID NO: 1 and it is noted that the claimed polynucleotides do not exist as an invention independent of their function in encoding a putative outer membrane protein. The actual structure or other relevant identifying characteristics of each nucleic acid that encodes a variant protein (i.e. homolog) having the claimed properties of the putative 98 kD protein can only be determined empirically by actually making every nucleic acid that encodes the recited variability (i.e. the instant 75% identity) and testing each to determine whether it encodes a protein having the particularly disclosed properties of an 98kDprotein. As noted in the Guidelines at Section I.A (2). There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonable predict the complete structure of the claimed invention from its function. There is no written description support for a method of preventing Chlamydial infection as claimed.

Applicants specification proposes the converse, yet still does not meet the requirements for an adequate written description of the claimed invention. Applicants propose that the skilled artisan is to modify a known nucleic acid sequence encoding a known protein sequence and that modification would still describe applicants invention as a 98kDprotein as disclosed. The 98kD outer membrane protein is uncharacterized by this specification and is not asserted to belong to any known family of proteins. The protein has specific biological properties dictated by the structure of the protein and the corresponding structure of the structural gene sequence which encodes it. There must be some nexus between the structure of a gene sequence and the structure of the protein encoded, and the function of that encoded protein. However, similar function cannot be predicted from the modification of the structure of the gene or in this case the gene encoding the protein. Applicants have not shown that, by modifying a reference sequence encoding a reference polypeptide as claimed, will automatically predict the production of a 98kDouter membrane protein as disclosed. While it is true that, due to the nature of codon degeneracy, applicant may take a reference sequence and modify that sequence to be a different nucleic acid sequence, yet still have that nucleic acid encode the same putative 98 kD protein. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number 98kDpolypeptides, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. With the exception of an isolated polynucleotide comprising SEQ ID NO: 1 and an isolated polynucleotide comprising of a nucleotide sequence encoding SEQ ID NO: 14, fragments thereof and associated, vectors, vaccines, fusions etc dependent thereon, the skilled artisan cannot envision the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides and therefore conception cannot be not achieved until reduction to practice has occurred, regardless

of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chuaai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

12. Claims 2, 8-14, 16, 18-19 and 36 are also rejected under 35 U.5.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising SEQ ID NO: 1, vector comprising the nucleic acid, SEQ ID NO: 1 and host cell comprising the said vector, the specification does not reasonably provide enablement for any DNA vaccines or any immunogenic or pharmacological composition comprising SEQ ID NO: 1, or variants and fragments and a sequence which encodes a 75% identical polypeptide variant thereof and a method of preventing Chlamydial infection using said nucleic acids. The specification is not enabled for any variants of a polynucleotide comprising SEQ ID NO: 1 (i.e. the instant a sequence which encodes a polypeptide encoded by SEQ ID NO: 1 or) thereof or probes/primers based on any of these recited variants, method of producing the recited variants and a method for preventing Chlamydia infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims since there is no written description support for the claimed invention.

Claim Rejections - 35 U.S. C. § 112, second paragraph

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

14. Claims 2, 8-14, 16, 18-19 and 36 are rejected under 35 U.5.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 8-14, 16and 36 are indefinite because the claim recites a sequence which encodes a polypeptide encoded by SEQ ID NO: 1, however SEQ ID NO: 1 has at a minimum 6 reading frames, each encoding its own distinct polypeptide. Therefore, the metes and bounds of the claimed nucleic acid is unclear.

Claim 8 is vague and indefinite for the recitation of "at least one first nucleic acid". It is not clear what are the metes and bounds of at least one first nucleic acid as written.

Claim 8 recites the limitation " each first nucleic acid " in line 19. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation " each first nucleic acid " in line 18. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 is vague and indefinite for the recitation of "second nucleic acid" and It is not clear what are the metes and bounds of second nucleic acid as written.

Claim 14 is vague in reciting "additional Chlamydia polypeptide". It is not clear what are the metes and bounds of additional Chlamydia polypeptide as written because claim 13 does not recite the source of the polypeptide.

Claims 18-19 recite in the alternative "complementary or antisense sequence of said nucleic acid molecule". However, these terms have the same meaning and are redundant. Applicants are directed to amend the claim to choose one means of claiming the opposite nucleic acid strand.

Claim Rejections - 35 USC 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

16. Claims 18-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60- -- 62).

The claims are drawn to isolated nucleic acid sequences, which are probes and primers having variable lengths (5-100 nucleotides) based on SEQ ID NO: 1 or complements thereof.

Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60-62) each disclose a wide variety of probes, primers and linkers of over 10 nucleotides in length. Thus the disclosed random primers, probes and linkers anticipated the instant claims. The primers and linkers have been applied as relevant to the restriction map provided for SEQ ID NO: 1.

Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), disclose kits containing isolated packaged random 6-mer primers and random 9-mer primers. The random primer kits contain all possible 6 mer and 9 mer sequences for priming DNA sequences for labeling. The prior art anticipated the claimed invention.

17. Claims 2, 8 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kalman et al, (Kalman et al. (Accession No: AE001641, 'Submitted 12/1/98' & 'Nat. Genet. 1999, 21(4): 385-389' and reference A 57 on PTOL-1449).

Claims are drawn to a nucleic acid molecule comprising SEQ.ID.NO: 1, pharmaceutical and vaccine composition comprising SEQ.ID.NO: 1.

Kalman et al disclose a nucleic acid sequence from C. pneumoniae that is 98.1 % identical to SEQ ID NO: 1. Kalman et al anticipated the claimed inventions. Therefore, the prior art meets the limitations of claimed nucleic acid molecule comprising SEQ.ID.NO: 1.

The examiner is viewing the vaccine composition as a composition comprising a nucleic acid sequence (SEQ.ID.NO: 1).

It is acknowledged that weight is given to every term in claims 8 and 16. This is why the instant claims 8 and 16 drawn to vaccines and pharmaceutical composition are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same nucleic acid and formulations thereof as claimed.

Status of Claims

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

2/14/03

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